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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,896	02/15/2001	Mark I. Greene	PENN-0743	3799

26259 7590 10/02/2002

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,896

Applicant(s)

GREENE ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*

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Response to Amendment

1. The amendment filed 6/19/2002 has been entered.
2. Regarding the restriction requirement made in the Office action mailed 2/27/2002, Applicants argue that the restriction requirement is not proper because for restriction requirement to be proper, two criteria must be met. First, the invention must be independent and distinct as claimed and second, there must be a serious burden on the examiner if the invention is not restricted. The reasons for the restriction requirement are explicitly set forth in the Office action mailed 2/27/2002 that Inventions I and II are distinct, because the product, Invention II, claims 2-3 and 5-6 can be used in immunoassay, while the method, Invention I, claims 1 and 11-14 can be practiced with different material, for example, tissue sample and Invention III-V are drawn to different methods because these inventions have different method steps based upon the different preamble. Therefore, the restriction requirement is proper.
3. The objection of Specification is withdrawn because of the amendment.
4. The rejection of claims 11-14 under 35 U.S.C. §112, second paragraph is withdrawn because of the amendment filed 6/19/2002.
5. The rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Suzuki et al. (Jpn. J. Cancer Res. Vol. 86, pg. 885-889) is withdrawn because of the amendment. However, the language "contacting the amplified oligonucleotide with a fluorescent dye which binds to

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RNA directly" is not supported in the specification and it constitutes new matter. Whenever, the new matter is removed, the original rejection will again be introduced.

6. Claims 11-14 remain rejected under 35 U.S.C. §103(a) over Suzuki et al. (Jpn. J. Cancer Res. Vol. 86, pg. 885-889) in view of Eberwine et al. (5,922,553) and Zeytinoglu et al. (5,874,226).

Applicants argue that none of the references teach the additional steps but Zeytinoglu et al. disclose in situ immunodetection of antigens involving polymerase chain reaction (See column 1, lines 36-54), other amplification technologies are applicable, including two steps (See column 5, lines 14-16) and the PCR amplification method shown is especially advantageous where the amount of antigen detected is very small (See column 5, lines 47-49). Therefore, one of ordinary skill in the art would have been motivated to add one more steps, either a reverse transcriptase based reaction or a replicase based reaction with a reasonable expectation of success.

Applicant's arguments filed 6/19/2002 have been fully considered but they are not persuasive. The rejection is maintained.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention since the language "contacting the amplified oligonucleotide with a fluorescent dye which binds to RNA directly" is not supported in the specification. The paragraph on page 11, lines 24 to page 12 lines 1-3 only indicates that the RNA is labeled with fluorescent dye. Thus, it constitutes new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 is vague and indefinite because it is unclear what is meant by the language "directly" which describes the binding of the RNA to the amplified oligonucleotide.

Clarification is required.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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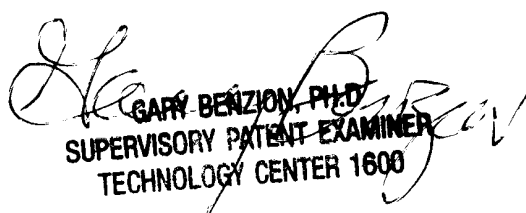
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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 10, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600